

HUBR-1206 (10202655)

IN THE CLAIMS

27. (previously presented) A sustained release form comprising one or more cationogenic polymers,

(b)  $\alpha$ -lipoic acid or/and a derivative thereof and

(c) at least one acid different from (b).

28. (previously presented) A sustained release form as claimed in claim 27, wherein that component (B) comprises at least one of a racemic  $\alpha$ -lipoic acid or an enantiopure R-(+)- $\alpha$ -lipoic acid or S-(-)- $\alpha$ -lipoic acid.

29. (previously presented) A sustained release form as claimed in claim 27, wherein that component (b) comprises a racemic dihydrolipoic acid, an enantiopure (+) – dihydrolipoic acid or (-) – dihydrolipoic acid or mixtures thereof.

30. (previously presented) A sustained release form as claimed in claim 27, wherein that the  $\alpha$ -lipoic acid or dihydrolipoic acid is present in whole or in part in the form of the salts thereof.

31. (previously presented) A sustained release form as claimed in claim 30, wherein that the salts of  $\alpha$ -lipoic acid or dihydrolipoic acid comprise cations selected from the group consisting of alkali metals and alkaline earth metals.

32. (previously presented) A sustained release form as claimed in claim 30, wherein

HUBR-1206 (10202655)

that the salts of  $\alpha$ -lipoic acid or dihydrolipoic acid comprise cations from the group of iron, copper, zinc, palladium, vanadium and selenium.

33. (previously presented) A sustained release form as claimed in claim 30, wherein that the salts of  $\alpha$ -lipoic acid or dihydrolipoic acid comprise organic cations selected from the group consisting of open-chain or cyclic ammonium, benzylammonium, diisopropylammonium, triethylammonium, cyclohexylammonium, and complex cations, where appropriate with a metallic central atom such as, for example, iron (III), chromium (III) or cobalt (II) and neutral, cationic or anionic ligands such as, for example, water, ammonia, carbonyl, cyano or nitroso, or oxo cations such as oxovanadium(V) (VO<sub>2</sub><sup>+</sup>) or oxovanadium(IV) (VO<sub>2</sub><sup>+</sup>).

34. (previously presented) A sustained release form as claimed in claim 27, wherein component (a) is at least one cationogenic polymer selected from the group consisting of chitosan (poly-D-glucosamine), chitosan salts, poly-L-lysine, basic lectins and biopolymers of plant, animal or synthetic origin.

35. (previously presented) A sustained release form as claimed in claim 27, wherein the proportion of cationogenic polymer is from 0.1 to 90% by weight, in particular 5 to 50% by weight, in each case based on the weight of components (a), (b) and (c) in the sustained release form.

36. (previously presented) A sustained release form as claimed in claim 27, wherein said  $\alpha$ -lipoic acid component is present in proportions of from 0.1 to 99% by weight, in particular in proportions of from 20 to 90% by weight, in each case based on the weight of

HUBR-1206 (10202655)

components (a), (b) and (c) in the sustained release form.

37. (previously presented) A sustained release form as claimed in claim 27, wherein acid component (c) comprises an organic or inorganic Brønstedt acid, in particular acetic acid selected from the group consisting of acetic acid, hydrochloric acid and glutamic acid.

38. (previously presented) A sustained release form as claimed in claim 27, wherein acid component (c) comprises an organic or inorganic Lewis acid, in particular carbon dioxide,  $\text{Ca}^{2+}$  or  $\text{Fe}^{2+}$ .

39. (currently amended) A sustained release form as claimed in claim 27 1, wherein that the acid component (c) comprises a complex acid, in particular hexaaquoaluminum hexaaquoaluminum (III)  $[\text{Al}(\text{H}_2\text{O})_6]^{3+}$  or hexacyanoiron(II) acid  $[\text{H}_4(\text{Fe}(\text{CN})_6)]$   $[\text{H}_4(\text{Fe}(\text{CN})_6)]$ .

40. (previously presented) A sustained release form as claimed in claim 27, wherein the acid component (c) comprises a polymeric acid, an isopolyacid, heptamolybdic acid ( $\text{H}_6\text{Mo}_7\text{O}_{24}$ ), or a heteropolyacid.

41. (previously presented) A sustained release form as claimed in claim 27, wherein said acid component (c) is present in proportions of from 0.001 to 80% by weight based on the weight of components (a), (b) and (c) in the sustained release form.

42. (previously presented) A sustained release form as claimed in claim 27, further comprising at least one formulation aid, selected from the group consisting of fillers, lubricants, flow aids, mold release agents, plasticizers, blowing agents, stabilizers, colorants, extenders,

HUBR-1206 (10202655)

binders, disintegrants, wetting agents, glidants and non-stick agents.

43. (previously presented) A sustained release form as claimed in claim 42, wherein that is comprises fillers inorganic fillers such as, for example, oxides of magnesium, aluminum, silicon or titanium, microcrystalline cellulose and cellulose powder, starches and derivatives thereof (for example maltodextrins), lactose, mannitol and calcium disphosphate, as lubricants stearates of aluminum and calcium, talc or silicones, as flow aids magnesium stearate, colloidal silica, talc or Aerosil, as plasticizers low molecular weight polyalkylene oxides, low molecular weight organic plasticizers such as glycerol, pentacrythritol, glycerol monoacetate, diacetate or triacetate, propylene glycol, sorbitol or Na diethyl sulfosuccinate, as colorants azo dyes, (in)organic pigments or natural coloring agents, or other conventional excipients such as sugar (alcohols), polymers, phosphates and surfactants, preferably in respective proportions between 0.02 to 50% by weight, based on the total weight.

44. (previously presented) A method of preparing the sustained release form of claim 42 comprising the steps of sustained release

- 1) Mixing component (a) with component (c), preferably in the ratio 1:2 to 1:4 by weight, then adding water to this mixture, and homogenizing the resulting mixture with the  $\alpha$ -lipoic acid component (b) in the preferred mixture: component (b) ratio of 1:0.3-0.003 by weight,
- 2) subjecting the homogenate from 1) to a wet granulation;
- 3) drying the wet granulates at temperatures between 5 and 50°C to form dry granulates; and

HUBR-1206 (10202655)

4) tableting the dry granules.

45. (previously presented) A food supplement comprising the sustained release form as claimed in claim 27.

46. (previously presented) A medicament comprising the sustained release form of claim 27 for producing a medicament.

47. (previously presented) A cosmetic comprising the sustained release form of claim 27.

48. (previously presented) A method of administering  $\alpha$ -lipoic acid to a subject comprising administering the sustained release form of claim 27 to a subject said administering being oral, dermal, parenteral, rectal, vaginal topical administrations.

49. (previously presented) The medicament of claim 46, wherein said medicament is a gel, semisolid dosage form or a solid solution.

50. (previously presented) A method for improving the absorption of  $\alpha$ -lipoic acid and derivatives thereof in a subject comprising preparing said sustained release form of claim 27 and administering said sustained release form to said subject, wherein controlled release of  $\alpha$ -lipoic acid or a derivative thereof.

51. (previously presented) A method of providing controlled delivery of  $\alpha$ -lipoic acid or a derivative thereof in a subject comprising administering to said subject the sustained release form of claim 27 wherein said sustained release form provides controlled release of an active

HUBR-1206 (10202655)

ingredient for a period of more than about 8 hours.

52. (previously presented) A method for increasing the bioavailability of  $\alpha$ -lipoic acid or/and derivatives thereof comprising preparing the sustained release form of claim 27 and administering the sustained release form to a patient.